

**Do You REALLY Know When  
and How Much Insulin  
Your Patients are Taking?**

**Smart Dosing Monitors Can Help.**

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- Notice of Requirements For Successful Completion
  - Please refer to learning goals and objectives
  - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
- Presenter's Conflict of Interest (COI) and Financial Relationship Disclosures:
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  - Advisory Board: Capillary Bio, Companion Medical, Glooko, Eli Lilly,
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- Companion Medical has provided an honorarium for delivery of this program.

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### Objectives

- ✓ Delineate the clinical challenges among insulin pen users and their providers
- ✓ Describe the features of the various “smart” insulin pen devices
- ✓ Detail the clinical utility and limitations associated with “smart” pen devices

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### Insulin Use in the United States

- Approx. 8 Million Insulin Users
  - 1.6M type-1
  - 6.1M type-2
    - 1.6M taking rapid insulin
  - 3.2M *take insulin multiple times daily*
  - 80% take insulin by INJECTION (pen/syringe)

Source: Centers for Disease Control and Prevention

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### Management challenges faced by people who inject insulin

- Data logging
- Missed doses
- Meal dose calculations
- Stacking
- Double-Dosing
- Spoilage
- Complexity of add-ons



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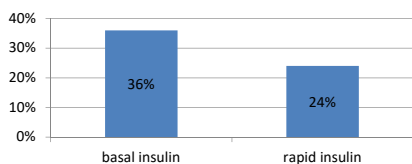
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### Management challenges faced by people who inject insulin

- Missed / Forgotten Doses by Adults



Source: Munshi, et al. Diabetes Care, 3/12/19. <https://doi.org/10.2337/dc18-1631>.

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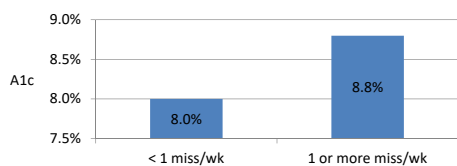
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### Management challenges faced by people who inject insulin

- Impact of missed meal doses in youth



Source: Burdick, et al. Pediatrics, vol 113 No 3, March 2004.

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### Management challenges faced by people who inject insulin

(computer-modeled study for people w/T1D)

- ~ 2 missed bolus doses/week : ↑ A1c .3-.4%
- ~ 2 missed basal doses/week: ↑ A1c .2-.3%
- ~ 38% missed bolus doses/week: ↑ A1c 1.8%

Rendelov et al, Journal of Diabetes Science & Technology, Vol 2, Issue 2, March 2008

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### Management challenges faced by people who inject insulin

- Numeracy Issues
  - 25% unable to identify their BG targets
  - 56% unable to count carbohydrate grams using a food label
  - 59% unable to calculate insulin dose based on grams of carbohydrate and BG

Marden et al. Diabetes Med 29:662-669, 2011; Osborn et al. J Health Comm 15:146-158, 2010; Cavanaugh et al. Diabetes Care 32:2149-2155, 2009.



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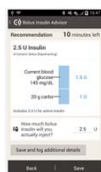
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### Management challenges faced by people who inject insulin

Use of dosing Advisor software by people w/T1

- A1c reduction of 0.6% after 12 months
- 19% increase in time in-range (70-150)
- No change in nocturnal hypoglycemia
- No change in total daily insulin or weight



Garg et al. Diabetes Technology & Therapeutics, Vol 10, No 5, 2008.



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### Challenges faced by CLINICIANS of people who inject insulin

- Insufficient Information
  - Lack of dosage logs
  - Lack of other data
- Inaccurate Information
  - Accidental
  - Intentional
- Time Limits for Training, Data Integration



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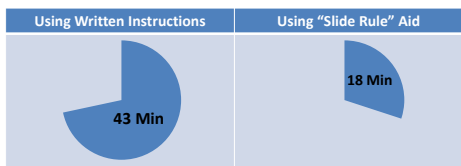
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### Challenges faced by CLINICIANS of people who inject insulin

Time required to teach dosage adjustments



Kaufman et al, Diabetes Care, Vol 22, No 8, August 1999

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### Smart Pen Technologies TO THE RESCUE!



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### Smart Pen Technologies: Timesulin (Bigfoot Biomedical)

- Tracks time since last dose was delivered
- Based on removal/replacement of device from pen
- Fits most disposable pens
- Not yet cleared by FDA



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### Smart Pen Technologies: Timesulin



**Issues Addressed:**

- ✗ Missed Doses
- ✓ Double Dosing
- ✗ Dose Calculations
- ✗ Bolus Stacking
- ✗ Spoilage
- ✗ Logging Accuracy
- ✗ Logging Detail
- ✗ Training Time
- ✓ Complexity

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### Smart Pen Technologies: Clipsulin (Diabnext)

- Counts audible clicks, displays last dose
- Works with most commercially-available pens
- 1/2- or 1-unit settings; +/- buttons for manual adjustment
- Automatic bluetooth transmission of doses to smartphone app
- HCP platform for viewing data
- Not yet FDA-cleared



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### Smart Pen Technologies: Clipsulin



**Issues Addressed:**

- ✗ Missed Doses
- ✓ Double Dosing
- ✗ Dose Calculations
- ✗ Bolus Stacking
- ✗ Spoilage
- ✓ Logging Accuracy
- ✗ Logging Detail
- ✗ Training Time
- ✓ Complexity

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### Smart Pen Technologies:

#### GoCap (Common Sensing)

- Attaches to Lantus and Apidra disposable pens
- Tracks doses and units left in pen
- Missed dose alerts
- Temperature alerts
- Wireless upload to smartphone app; user can enter BG & carbs
- Commercial version available in US mid-2020



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### Smart Pen Technologies: GoCap



#### Issues Addressed:

- ✓ Missed Doses
- ✓ Double Dosing
- ✗ Dose Calculations
- ✗ Bolus Stacking
- ✓ Spoilage
- ✓ Logging Accuracy
- ?? Logging Detail
- ✗ Training Time
- ✗ Complexity

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### Smart Pen Technologies:

#### NovoPen Echo (Novo Nordisk)

- Durable pen
- Takes 3.0 ml cartridges of Novolog
- Doses in 1/2-unit increments
- Displays last dose, time since last dose
- FDA-cleared



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**Smart Pen Technologies:**  
**NovoPen Echo/Plus (Novo Nordisk)**

- Durable pen
- Takes 3.0 ml cartridges of Toujeo, Tresiba, Novolog, Fiasp
- Doses in ½-units
- Displays last dose, time since last dose, IOB
- 800-dose memory
- Near Field Communication (scan) for downloading
- Not yet FDA-cleared; Launched in Europe 2019



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**Smart Pen Technologies:**  
**NovoPen Echo / Plus**

**Issues Addressed:**

- ✗ Missed Doses
- ✓ Double Dosing
- ✗ Dose Calculations
- ✗ Bolus Stacking
- ✗ Spoilage
- ✓ Logging Accuracy
- ✗ Logging Detail
- ✗ Training Time
- ✓ Complexity



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**Smart Pen Technologies:**  
**InPen (Companion Medical)**

- Prescription item
- Durable pen, takes Humalog or Novolog 3ml cartridges (different pens)
- Doses in ½-units
- Temperature monitor
- Bluetooth connection to smartphone app; "prime" doses factored out
- Customizable dose calculator
- Displays & adjusts for IOB
- Generates detailed PDF log reports
- Missed bolus and basal dose reminders
- FDA-cleared, prescription required



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**Smart Pen Technologies: InPen**



Issues Addressed:

- ✓ Missed Doses
- ✓ Double Dosing
- ✓ Dose Calculations
- ✓ Bolus Stacking
- ✓ Spoilage
- ✓ Logging Accuracy
- ✓ Logging Detail
- ✓ Training Time
- ✗ Complexity

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**Other Devices In Development**

- Novo Nordisk Bluetooth FlexTouch Pen Attachment
- BioCorp “Easylog” smart pen cap
- Lilly integrated smartpen/Dexcom/smartphone app
- Pendiq Digital Pens

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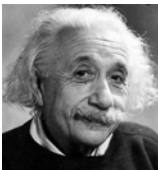
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**Insights to derive from smart dose monitor data**



- Were doses actually taken?
- When were they taken?
- How much was taken?
- Were dosage calculations correct?
- Are the current dosing formulas working?

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**GET THE POINT!**



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**Questions?**

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